

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WASHINGTON

BATES DRUG STORES, INC.,

Plaintiff,

v.

ERIC H. HOLDER, JR., Attorney  
General of the United States,  
United States Department of  
Justice; MICHELLE M. LEONHART,  
Administrator Drug Enforcement  
Administration, United States  
Department of Justice; and DRUG  
ENFORCEMENT ADMINISTRATION, United  
States Department of Justice,

Defendants.

NO. CV-11-0167-EFS

**ORDER GRANTING TEMPORARY  
RESTRAINING ORDER AND  
SETTING PRELIMINARY  
INJUNCTION HEARING**

A hearing occurred in the above-captioned matter on May 4, 2011, in Spokane, Washington. Jeffrey Bornstein, LEEANNE Hartmann, and Todd Reuter appeared on Plaintiff Bates Drug Stores, Inc.'s ("Bates") behalf. Andrew Biviano and Larry P. Cote appeared on behalf of Defendants Eric H. Holder, Jr., Michelle M. Leonhart, and the Drug Enforcement Administration ("DEA"), who received notice of the lawsuit and instant motion. Before the Court was Plaintiff's Motion for Temporary Restraining Order (ECF No. [3](#)), filed April 27, 2011. Bates seeks a temporary order preventing Defendants from enforcing a March 30, 2011 order ("Suspension Order") (ECF No. 1, Ex. 1) that immediately suspended

1 Bates' registration to distribute controlled substances. The DEA opposes  
2 the motion. After reviewing the submitted material and relevant  
3 authority and hearing from counsel, the Court was informed and granted  
4 Bates' motion. This Order memorializes and supplements the Court's oral  
5 rulings.

6 **A. Background**

7 Bates is comprised of two small employee-owned pharmacies operating  
8 in Spokane, Washington: one pharmacy serves "retail" customers (such as  
9 individuals and physicians), while the other serves institutions such as  
10 long-term care facilities. Both are registered with the DEA to dispense  
11 controlled substances in Schedules II-IV of the Controlled Substances  
12 Act, 21 U.S.C. § 801 et seq. ("CSA"), and thus are subject to DEA  
13 regulation and oversight.

14 The CSA establishes controls on import, export, manufacture, and  
15 distribution of controlled substances. 21 U.S.C. § 801 et seq.; 21  
16 U.S.C. § 951 et seq. The CSA requires all controlled substance  
17 distributors to register with the DEA. *Id.* § 822; see also 21 C.F.R. §  
18 1301.11 (DEA regulations requiring registration). The DEA has the  
19 authority to revoke such registration if, for example, the registrant  
20 acts in a manner inconsistent with the public interest. 21 U.S.C. §  
21 824(a) (articulating five grounds for revoking or suspending a  
22 registration). Before suspending or revoking the registration, the DEA  
23 must issue an order to show cause setting forth the DEA's basis for  
24 initiating proceedings and provide an administrative hearing not less  
25 than thirty days after the date the show-cause order was served. *Id.* §  
26 824(c).

1 The DEA may, in its discretion, suspend any registration immediately  
2 (before any administrative hearing), if it finds that a registrant's  
3 continued registration would pose "an imminent danger to the public  
4 health or safety." *Id.* § 824(d). As with § 824(a) suspensions, the DEA  
5 must provide a basis for its suspension in the order to show cause. *Id.*;  
6 21 C.F.R. § 1301.36(e). A § 824(d) suspension remains in effect until  
7 the DEA issues a final order unless the suspension is withdrawn by the  
8 Attorney General or dissolved by a court of competent jurisdiction. 21  
9 U.S.C. § 824(d).

10 On November 15-18, 2010, the DEA investigated and audited Bates'  
11 pharmacies. On March 30, 2011, the DEA issued a Suspension Order,  
12 immediately suspending Bates' registrations based on the belief that  
13 Bates' continued registration constituted an imminent danger to the  
14 public health and safety. In response, Bates submitted a hearing request  
15 to the Office of Administrative Law Judges (ALJ) on April 11, 2011, for  
16 review of the DEA's suspension and issuance of a final order.<sup>1</sup>

17 On April 27, 2011, Bates filed this action, challenging the  
18 Suspension Order as arbitrary, capricious, or inconsistent with law, and  
19 seeking to permanently enjoin the DEA from enforcing it. The instant  
20 motion was filed the same day.

## 21 **B. Discussion**

22 Bates asks the Court to issue a temporary restraining order to  
23 temporarily enjoin the DEA from enforcing the Suspension Order pending

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25 <sup>1</sup> The ALJ granted Plaintiff's request and set hearings on April 27,  
26 2011, and May 10, 2011. The parties anticipate the proceedings will  
conclude with the issuance of a final order in August 2011.

1 the outcome of a preliminary injunction hearing. A temporary restraining  
2 order may be issued to maintain the status quo if a plaintiff establishes  
3 he is "likely to succeed on the merits, that he is likely to suffer  
4 irreparable harm in the absence of preliminary relief, that the balance  
5 of equities tips in his favor, and that an injunction is in the public  
6 interest." *Winter v. Natural Res. Def. Council*, 129 S. Ct. 365, 374  
7 (2008). The Ninth Circuit uses a "sliding scale" under which the  
8 temporary restraining order may be issued if there are serious questions  
9 going to the merits and the balance of hardships tips sharply in the  
10 plaintiff's favor, along with satisfaction of the two other *Winter*  
11 factors. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1135  
12 (9th Cir. 2011).

13 The Court finds, on the brief record before it, that this standard  
14 has been met. First, Bates is likely to suffer irreparable harm in the  
15 absence of a temporary injunction enjoining the DEA's enforcement of the  
16 Suspension Order. Plaintiff will likely suffer harm in the form of lost  
17 revenue, harm to reputation and goodwill, fees and costs to remedy DEA  
18 findings, inability to obtain financing, and loss of third-party  
19 insurance providers. This harm is not speculative: Plaintiff's revenue  
20 dropped twenty percent (20%) in the first twenty (20) days following the  
21 Suspension Order, which translates to approximately \$70,000 loss in gross  
22 profits and \$50,000 loss in net profits each month. (ECF No. 7, p. 2-3.)  
23 A third-party billing provider already exercised its right to terminate  
24 its contract with Bates based on its license suspension. (ECF No 9, Ex.  
25 D.) Bates' president and CEO Robert Cordier insists layoffs are  
26 imminent. (ECF No. 9, p. 10.) The evidence shows that the Suspension

1 Order threatens Bates' very existence. Accordingly, irreparable harm is  
2 likely.

3 Second, Bates demonstrated serious questions relating to whether the  
4 DEA's finding of an imminent danger in its Suspension Order is arbitrary,  
5 capricious, or inconsistent with law. Under the Administrative Procedure  
6 Act (APA), the Court may set aside agency action that is "arbitrary,  
7 capricious, an abuse of discretion, or otherwise not in accordance with  
8 the law." 5 U.S.C. § 706(2)(a).<sup>2</sup> The Court must determine whether there  
9 is a rational connection between the underlying facts and the agency's  
10 decision. See *Burlington Truck Lines, Inc. v. United States*, 371 U.S.  
11 156, 168 (1962). As such, the Court's review of the facts is limited to  
12 the record before it at the time of the agency decision. *Beno v.*  
13 *Shalala*, 30 F.3d 1057, 1074 (9th Cir. 1994).

14 Here, the Court cannot consider the administrative record because  
15 one does not exist. And while the Suspension Order identifies numerous  
16 CSA violations discovered by DEA investigators at the pharmacies,<sup>3</sup> it  
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18 <sup>2</sup> In reviewing agency action, the Court is not authorized to  
19 "substitute its judgment for that of the agency" but must "consider  
20 whether the decision was based on a consideration of the relevant factors  
21 and whether there has been a clear error of judgment." *Citizens to*  
22 *Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416(1971).

23 <sup>3</sup> These include accepting returns of controlled substances from  
24 long-term care facilities, dispensing controlled substances to patients  
25 via prescriptions that did not contain all essential elements, refilling  
26 prescriptions for Schedule II controlled substances, dispensing  
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1 lacks specific facts demonstrating how those alleged violations were  
2 committed. Yet investigative sources confirm that Bates regularly  
3 accepted returns of controlled substances from its customers and then re-  
4 dispensed the controlled substances to others. (ECF No. 33-1, Ex. A, ¶  
5 16-19.) They also advise that Bates maintains inaccurate records and  
6 does not notify the DEA when it destroys returned controlled substances.  
7 *Id.* ¶ 20. On one occasion, Bates delivered a controlled substance to a  
8 long-term care facility in order to help the facility account for a  
9 shortage of tablets. *Id.* ¶ 13. Several additional record-keeping and  
10 prescription irregularities were discovered during the course of the  
11 investigation.

12 The Court understands these practices can result in the illegal  
13 diversion, theft, tampering with, or unintended dispensing of dangerous  
14 and addictive controlled substances to the general public for improper  
15 use. Nothing in the record demonstrates that any of those dangerous  
16 consequences occurred here. Additionally, the Court has serious doubts  
17 that the alleged violations, which Bates has been diligently working to  
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19 controlled substances before the prescription's issue date, repackaging  
20 and re-labeling controlled substances without being registered as a  
21 manufacturer, dispensing controlled substances to individual  
22 practitioners for their general office supply, failing to maintain  
23 prescriptions for controlled substances, failing to provide effective  
24 controls to guard against theft and diversion of controlled substances,  
25 and failing to maintain several required record keeping practices. (ECF  
26 No. 1, Ex. 1.)

1 correct,<sup>4</sup> pose an *imminent* danger to public health and safety. There is  
2 nothing in the record indicating that any Bates patient has been harmed  
3 or injured by the alleged violations. Nor is there any evidence that any  
4 controlled substance was dispensed to an improper individual, for an  
5 improper purpose, or in an improper dosage. Rather, the evidence shows  
6 that, despite these violations, the pharmacy acted with intent to provide  
7 quality care to its patients. On this record, the Court finds that  
8 serious questions exist as to whether the Suspension Order supports a  
9 finding that Bates' practices posed an imminent danger to the public  
10 health and safety. Accordingly, the Bates had demonstrated a likelihood  
11 of success on the merits.

12 Third, the balance of equities tips sharply in Bates' favor. The  
13 public has an interest in the DEA's continued diligent regulation of  
14 controlled substances, particularly those narcotics with street value.  
15 However, the Suspension Order was not issued in the abstract: it impacts  
16 the lives of countless human beings. Bates' interest in providing  
17 continued care to its customers in need of medicine, employment to its  
18 employees, and support to patients in long-term care and assisted-living  
19 facilities tips the balance of equities in Bates' favor.

20 Fourth, a temporary restraining order is in the public interest. As  
21 discussed, Bates was acting in the public interest to provide medical  
22 support for its patients. The alleged violations, although serious, are  
23 nevertheless correctable and have not harmed any customer, patient, or

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25 <sup>4</sup> After the November 2010 DEA audit, Bates hired an independent  
26 consultant and developed and implemented policies and procedures to  
remedy the DEA's concerns. (ECF No. 9, pp. 3-6.)

1 member of the public. As recognized above, the health and livelihood of  
2 countless individuals - both employees and patients - depend on Bates.  
3 Continuation of the Suspension Order would have an irreparable effect on  
4 all those people and, thus, a temporary restraining order is in the  
5 public interest.

6 **C. Conclusion**

7 For the reasons set forth above, the Court grants Plaintiff's  
8 request for a temporary restraining order. Accordingly, **IT IS HEREBY**  
9 **ORDERED:**

10 1. Plaintiff's Motion for Temporary Restraining Order (**ECF No. 3**)  
11 is **GRANTED**.

12 2. Plaintiff shall immediately post a **\$1,000.00 bond** with the  
13 Clerk's Office.

14 3. Defendants shall immediately return any registrations,  
15 licenses, or forms required to make this temporary restraining order  
16 effective.

17 4. Until the Court rules on the Motion for Preliminary Injunction  
18 or fourteen (14) days, whichever is earlier, **Defendants are enjoined from**  
19 **enforcing the March 30, 2011 Suspension Order that immediately suspended**  
20 **Bates' registration to distribute controlled substances (ECF No. 1, Ex.**  
21 **1).**

22 5. A preliminary injunction hearing is **SET for Wednesday, May 18,**  
23 **2011, at 9:00 a.m. in SPOKANE.**

24 6. **NO LATER THAN Monday, May 9, 2011, at 12:00 p.m.,** the parties  
25 shall meet and confer and file a report setting forth any matters to be  
26 /



1 addressed before or at the May 18, 2011 hearing.

2 **IT IS SO ORDERED.** The District Court Executive is directed to file  
3 this Order and provide copies of this Order to counsel.

4 **DATED** this 6<sup>th</sup> day of May 2011.

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7 EDWARD F. SHEA  
United States District Judge

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